K103648

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Innocoll
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510(k) Summary

Date Prepared: September 13th 2011

Submitter: Innocoll Pharmaceuticals,
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Dublin Road,
Athlone,
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Submission Correspondent: Aaron Wyse
Director of Regulatory Affairs
Tel: +353 (0) 87 0520845
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Proprietary Name: Collagen Powder

Common Name: Topical Wound Dressing

Device Classification:

Product Code:	KGN
Classification Name:	Dressing Wound Collagen
Regulatory Class:	Unclassified

Statement of Substantial Equivalence:
Collagen Powder is substantially equivalent in materials of construction and intended use to Collagen Sponge (K092805) and Collatek Powder (K012990). Collagen Powder has been evaluated for its biocompatibility which meets requirements and is therefore substantially equivalent to the predicates delineated in this submission. Collagen Powder is manufactured from the same ingredients used for the manufacture of Collagen Sponge (K092805).

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Intended Use:
Collagen Powder may be used for the management of wounds such as:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full-thickness & partial thickness wounds
- Abrasions
- Traumatic wounds
- 1st and 2nd degree burns
- Dehisced surgical wounds
- Exuding wounds

Description:
Collagen Powder is a collagen matrix in powder form intended for application as a wound management device. The product is supplied sterile for single use only.

Biocompatibility and Testing:
Evaluation of the biocompatibility of Collagen Powder was completed in line with the requirements of ISO 10993 -1: 2009. There are no new biocompatibility issues arising with the use of Collagen Powder; the materials of construction for Collagen Powder match Collagen Sponge (K092805).

Biochemical characterization of the collagen used to manufacture Collagen Powder was undertaken which characterized the collagen as being predominantly Type I collagen which is not denatured during the collagen rendering process.

Viral inactivation validation assessment was conducted on the collagen which demonstrates that the collagen material post processing can be assumed not to contain any pathogenic organisms.

Particle size analysis was conducted on the finished product which verified a particle size range for Collagen Powder.

Conclusion:
Collagen Powder is substantially equivalent to the predicate devices delineated in this submission and meets the requirements for premarket notification as defined in CFR21, Part 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Innocoll Pharmaceuticals, Ltd.
% Mr. Aaron Wyse
Directory of Regulatory Affairs
Midlands Innovation & Research Centre, Dublin Road
Athione, Co. Westmeath
Ireland

Re: K103648
Trade/Device Name: Collagen Powder
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 1, 2011
Received: September 6, 2011

SEP 14 2011

Dear Mr. Wyse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

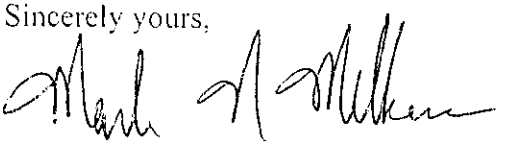
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103648

Statement of Indications for Use

510(k) Number (if known):

Device Name: Collagen Powder

Indications For Use: Collagen Powder may be used for the management of wounds such as:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full- & partial thickness wounds
- Abrasions
- Traumatic wounds
- 1st and 2nd degree burns
- Dehisced surgical wounds
- Exuding wounds

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103648